UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,289	03/01/2004	Kati A. Chevaux	1010/0102US4	9500

32260 7590 03/30/2011

NADA JAIN, P.C.
560 White Plains Road, Suite 460
Tarrytown, NY 10591

EXAMINER	
WINSTON, RANDALL O	

ART UNIT	PAPER NUMBER
1655	

NOTIFICATION DATE	DELIVERY MODE
03/30/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

paralegal@nadajain.com
nada@nadajain.com

Office Action Summary	Application No.	Applicant(s)	
	10/790,289	CHEVAUX ET AL.	
	Examiner	Art Unit	
	RANDALL WINSTON	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 January 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *75-115* is/are pending in the application.

4a) Of the above claim(s) *75-78* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *79-115* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement is a made of receipt and entry of the amendment filed on 01/17/2011.

Claims 79-115 have been examined on the merits (Claims 75-78 remains withdrawn from consideration.)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 79-115 stand rejected under 35 US 103(a) as being unpatentable over Romanczyk, Jr (US 5,554,645) in view Faendriks (Derwent Acc No 1997-525196, see abstract) for the same reasons set forth in the previous OFFICE ACTION which are restated below.

A food product (i.e. non-chocolate) comprising (i) cocoa polyphenol (i.e. a polyphenol compound of formula An of claim 32) and (ii) L-arginine in various amounts is claimed.

Romanczyk teaches a food composition comprising a cocoa polyphenol (i.e. a polyphenol compound of formula An of claim 32 is within figure 3 of Romanczyk, named (-) epicatechin)) is used for anti-cancer purposes. (see, e.g. figure 3, column 7 lines 20-27 and entire patent) [please note that since Applicant's instant specification provides

for very broad amount ranges of the instantly claimed ingredients therein - including from about 1 μg to about 10 g per unit dose of cocoa polyphenol and Romanczyk discloses high levels/percentages of cocoa polyphenol within such non-chocolate food compositions for inhibiting tumor growth for an anti-cancer purpose, Romanczyk claimed amounts/ranges would intrinsically provide the instantly claimed *in vivo* functional effect with respect to increasing nitric oxide, upon ingestion thereof]. Romanczyk, however, does not expressly teach that the active ingredient of L-arginine is contained within the claimed food composition nor does Romanczyk teach all the claimed forms of the food composition and all the claimed amounts/ranges used for an anti-cancer purpose.

Faendriks beneficially teaches that L-arginine can be used for anti-cancer purposes (see, e.g. abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Romanczyk's food composition to include the active ingredient of L-arginine as taught by Faendriks within Romanczky's food composition because the above combined teachings as a whole would create the composition comprising the combination of cocoa polyphenol and L-arginine having anti-cancer activity. Moreover, as discussed in MPEP Section 2114.06, "it is prima facie obvious to combine two or more compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to used for the same purpose". Furthermore, the adjustment of other conventional working conditions (e.g. the substitution of the claimed forms of the food composition such as non-chocolate pet

food and determining suitable amount/ranges of each active ingredient within the claimed composition), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Please note, the intended use of the above claimed composition (i.e. to induce a physiological increase in nitric oxide in human or veterinary animals) does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting (see, e.g., MPEP 2112).

Applicant's arguments have been carefully considered but they are not deemed persuasive. Applicant argues the cited reference of Faendriks does not teach the use of L-arginine for the same purpose as Romanczyk and the effects of L-arginine as an anti-tumor ingredient were unpredictable as evidenced within the Applicant's provided article by Kenneth Park to Examiner. Examiner disagrees with Applicant's argument because the Faendriks reference's abstract on page 1 expressly discloses that L-arginine can be used for anti-cancer purpose. Moreover, Romanczyk teaches a food composition

comprising a cocoa polyphenol (i.e. a polyphenol compound of formula An of claim 32 is within figure 3 of Romanczyk, named (-) epicatechin)) is used for an anti-cancer purpose. The Faendriks reference was cited by Examiner to remedy Romanczyk deficiency. Therefore, since as discussed in MPEP Section 2114.06, "it is prima facie obvious to combine two or more compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to used for the same purpose", it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Romanczyk's food composition to include the active ingredient of L-arginine as taught by Faendriks within Romanczky's food composition because the above combined teachings as a whole would create the instantly claimed composition comprising the combination of cocoa polyphenol and L-arginine used for the same purpose of having anti-cancer activity.

Moreover, Applicant argues that the claimed limitation of up to 3g of cocoa polyphenol must be given weight and that routine optimization of the prior art teaches away from the dosage level (i.e. up to 3g of cocoa polyphenol per unit dose) of the instantly claimed composition as evidenced within the Applicant's provided article by Molnar et al. to Examiner. Examiner disagrees with Applicant's argument because the claimed limitation of 3g of cocoa polyphenol per unit dose does not properly define as well as further limit the instantly claimed food composition. For example, if one of ordinary skill in the art creates and/or provides a composition and/or product comprising the claimed active ingredients such as cocoa polyphenol and l-arginine within claimed amounts/ranges of the composition (as reasonably suggested by the cited references,

as fully discussed above), one of ordinary skill in the art can utilize any arbitrary unit dose of that composition and/or product for such administration (e.g., a bite, a teaspoon full, etc). Therefore, Examiner considers that the claimed limitation of utilizing a unit dose up to 3g of the cocoa polyphenol does not properly define as well as further limit the instantly claimed food composition, per se. Thus, since the cited references of Romanczyk and Faendriks as a whole create the instantly claimed food composition comprising the combination of cocoa polyphenol and L-arginine used for the same purpose of having anti-cancer activity, the adjustment of this type of conventional working condition therein (e.g. determining suitable amount/ranges of each claimed ingredient within the claimed food composition), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Lastly, Applicant argues the recitation "effective to induce vasorelaxation in a human or a veterinary animal" is a structural claimed limitation. Examiner disagrees with Applicant's argument because Examiner maintains since the cited references of Romanczyk and Faendriks as a whole create the instantly claimed food composition, the intended use of the above claimed composition (i.e. to induce a physiological increase in nitric oxide in a human or veterinary animals) does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting (see, e.g., MPEP 2112).

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RANDALL WINSTON whose telephone number is (571)272-0972. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RW

/Christopher R Tate/
Primary Examiner, Art Unit 1655